



Medicines & Healthcare products
Regulatory Agency



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Dr Ferdousi Chowdhury
UNIVERSITY OF OXFORD
RESEARCH GOVERNANCE, ETHICS & ASSURANCE TEAM,
BOUNDARY BROOK HOUSE, CHURCHILL DRIVE, HEADINGTON
OXFORD
OX3 7GB
UNITED KINGDOM

10/12/2024

Dear Dr Ferdousi Chowdhury,

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:	CTA 21584/0423/001-0036
Eudract Number:	2020-001113-21
Product:	Hydrocortisone, RoActemra, Kineret , Dexamethasone , Prednisolone, Empagliflozin, Oseltamivir, Baloxavir, Sotrovimab, Molnupiravir, Nirmatrelvir/ritonavir
Protocol number:	NDPHRECOVERY
Substantial Amendment Code Number:	Substantial Amendment 36

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority accepts the proposed amendment to your clinical trial authorisation (CTA), received on 07/11/2024.

PHARMACEUTICAL - Remarks: Pharmaceutical conditions of approval.

Authorisation of your amendment is subject to the following condition(s):

1. A study-specific QP declaration for baloxavir marboxil clinical supply will be submitted with the next substantial amendment. The current QP declaration submitted refers to a different clinical trial.

If these conditions are met, the substantial amendment is accepted and you do not need to respond to this letter. If these conditions are not met, the substantial amendment is not accepted and therefore you cannot proceed with the implementation of the amendment.

You must inform the MHRA immediately if the above conditions are not met. All subsequent changes to the terms and conditions of this trial must be made as a request for a substantial amendment to this clinical trial authorisation.



For further information on the above points, please contact Fiona Law on fiona.law@mhra.gov.uk.

This amendment may therefore be made.

If applicable, you should ensure your trial details have been updated on the database where you have registered your trial.

You are reminded that from 1 January 2022 you will need to comply with the requirements specified in the following guidance, where applicable:

o Import of IMPs from listed countries to GB:

<https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries>

o Supply of IMPs to Northern Ireland:

<https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland>

o Substantial amendments to clinical trials:

<https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial>

Any required substantial amendment to your Clinical Trial Authorisation should be submitted and approved as soon as possible and before 1 January 2022.

Yours sincerely,

**Clinical Trials Unit
MHRA**